ORAL ARGUMENT NOT YET SCHEDULED

Docket No. 24-1151
Consolidated with Docket Nos. 24-1185, 24-1182, 24-1202, 24-1237

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TEXAS CHEMISTRY COUNCIL, et al.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,

Respondents,

OLIN CORPORATION, et al.

Intervenors.

On Petition for Review of Final Action by the
U.S. Environmental Protection Agency

JOINT OPENING BRIEF OF PETITIONERS TEXAS CHEMISTRY COUNCIL, AMERICAN CHEMISTRY COUNCIL, AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS, AND AMERICAN PETROLEUM INSTITUTE

Rafe Petersen
Meaghan Colligan
HOLLAND & KNIGHT LLP
800 17th Street N.W.
Suite 1100
Washington, D.C. 20006
Rafe.Petersen@hklaw.com
Meaghan.Colligan@hklaw.com
Tel.: (202) 419-2481

Attorneys for Petitioners, Texas Chemistry Council and American Chemistry Council

David Y. Chung
CROWELL & MORING LLP
1001 Pennsylvania Avenue N.W.
Washington, D.C. 20004
DChung@crowell.com
Tel.: (202) 624-2567

Attorney for Petitioners, American Fuel & Petrochemical Manufacturers and American Petroleum Institute

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), counsel for Texas Chemistry Council, American Chemistry Council, American Fuel & Petrochemical Manufacturers, and American Petroleum Institute certify as follows:

(A) Parties and Amici.

Petitioners: The Petitioners to this case are American Chemistry Council; Texas Chemistry Council; American Fuel & Petrochemical Manufacturers; American Petroleum Institute ("**Petitioners**") and United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO; International Association of Machinists and Aerospace Workers; Worksafe, Inc. ("**Labor Petitioners**").

Respondents: The Respondents to this case are the United States Environmental Protection Agency and Administrator Michael Regan.

Petitioner-Intervenors: The Petitioner-Intervenor to this case is Olin Corporation.

Respondent-Intervenors: The Respondent-Intervenors to this case are Sierra Club and Alaska Community Action on Toxics.

(B) Rulings Under Review. The Petition for Review challenges the U.S. Environmental Protection Agency's final agency action titled "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act", which appears

in the Federal Register at 89 Fed. Reg. 37,028 (May 3, 2024) (the "**Rule**"). The Rule is codified at 40 C.F.R. Part 702, Subpart B.

(C) Related Cases.

Each of the petitions for review consolidated with Case No. 24-1185 is related. These cases consist of the following, none of which has been previously reviewed by this or any other Court:

- *United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union v. U.S. Environmental Protection Agency*, Case No. 24-1151
- *International Association of Machinists and Aerospace Workers v. U.S. Environmental Protection Agency,* Case No. 24-1182
- *Worksafe, Inc. v. U.S. Environmental Protection Agency,* Case No. 24-1202
- *American Fuel & Petrochemical Manufacturers and American Petroleum Institute v. U.S. Environmental Protection Agency*, Case No. 24-1237

CORPORATE DISCLOSURE STATEMENT

Under Federal Rule of Appellate Procedure and D.C. Circuit Rule 26.1, Petitioners hereby provide the following disclosures:

American Chemistry Council ("**ACC**") states that it has no parent corporation and does not issue stock to the public, and thus no publicly held corporation owns 10% or more of its stock. ACC is a "trade association" under Circuit Rule 26.1.

Texas Chemistry Council ("**TCC**") states that it has no parent corporation and does not issue stock to the public, and thus no publicly held corporation owns 10% or more of its stock. TCC is a "trade association" under Circuit Rule 26.1.

American Fuel & Petrochemical Manufacturers ("**AFPM**") states that it has no parent corporation and does not issue stock to the public, and thus no publicly held corporation owns 10% or more of its stock. AFPM is a "trade association" under Circuit Rule 26.1.

American Petroleum Institute ("**API**") states that it has no parent corporation and does not issue stock to the public, and thus no publicly held corporation owns 10% or more of its stock. API is a "trade association" under Circuit Rule 26.1.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Legislative Materials

Federal Register

Other Authorities

GLOSSARY OF ABBREVIATIONS

ACC	American Chemistry Council
AFPM	American Fuel & Petrochemical Manufacturers
APA	Administrative Procedure Act
API	American Petroleum Institute
ECEL	Existing Chemical Exposure Limit
EPA	United States Environmental Protection Agency
OSHA	Occupational Safety and Health Administration
OSH Act	Occupational Safety and Health Act
PEL	Permissible Exposure Limit
PPE	Personal Protective Equipment
TCC	Texas Chemistry Council
TSCA	Toxic Substances Control Act

INTRODUCTION

Chemicals serve as the building blocks for every aspect of our daily lives – from the clothes we wear, to the products we consume, and the equipment we utilize to help keep us safe. In 1976, Congress enacted the Toxic Substances Control Act ("**TSCA**") authorizing the U.S. Environmental Protection Agency ("**EPA**") to identify risks posed by chemicals to human health and the environment. Congress intended TSCA to *supplement* other statutes and regulations, not subsume them.

Petitioners are trade associations whose member companies manufacture, process, distribute, sell, and use chemicals. As such, Petitioners are regulated by TSCA and support chemical regulation that is comprehensive, reasonable, based on current science, and consistent with Congressional intent.

In 2016, Congress amended TSCA ("**2016 Amendments**") to establish a process for EPA to evaluate the risks of existing chemicals. EPA is required to first prioritize certain existing chemicals as "high priority" ("**Prioritization**"). Then, EPA is required to evaluate the risks associated with certain uses of those high priority chemicals ("**Risk Evaluation**"), and issue a determination as to whether there is an unreasonable risk from any of the identified uses ("**Risk Determination**").[1] Following the Risk Determination, TSCA directs EPA to

[1] Collectively, the Risk Evaluation and Risk Determination stages are referred to herein as the "**Risk Evaluation Process**".

implement regulations, to the extent necessary, to address unreasonable risks identified for specific uses during the Risk Evaluation Process ("**Risk Management**"). The 2016 Amendments required the agency to promulgate procedural regulations to describe how chemicals would undergo Risk Evaluation. These regulations were published in 2017 ("**2017 Rule**"). *See* "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act," 82 Fed. Reg. 33,726 (July 20, 2017).

EPA's 2017 Rule was consistent with the plain language of TSCA. EPA recognized that TSCA instructs the agency to complete Risk Evaluations by focusing on the specific conditions of use of a chemical, and issuing separate Risk Determinations for each of the relevant uses ("**Use-By-Use Approach**"). In determining which uses to assess in the Risk Evaluation, EPA's 2017 Rule indicated it would evaluate the uses that raise the greatest potential for risk so it would have the capacity to comply with statutory deadlines. Put differently, the 2017 Rule required EPA to identify the specific uses[2] for each chemical EPA sought to evaluate, concentrating on categories of uses of the chemical throughout key lifecycle stages such as manufacturing, processing, distribution, and disposal.[3]

[2] TSCA defines and refers to these specific uses of chemicals as the "conditions of use", which is used interchangeably with "use" herein. 15 U.S.C. § 2602(4).
[3] In the Risk Evaluation Process, these categories of uses are broken down into the more specific conditions of use. For example, in the Risk Evaluation for methylene

In May 2024, EPA upended the Risk Evaluation Process with the rule challenged here. *See* Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 89 Fed. Reg. 37,028 (May 3, 2024) ("**Rule**"). In two critical ways, the Rule completely reversed EPA's prior interpretation of TSCA's directive to complete its Risk Evaluation Process by focusing on conditions of use. First, rather than focusing on uses with the greatest exposure potential, which is required by the plain language of TSCA, EPA has now erroneously concluded that TSCA requires review of *every possible use* of a chemical in its Risk Evaluations ("**All Conditions of Use Approach**"). Second, EPA reversed it prior position on Risk Determinations – now stating that Congress requires Risk Determinations based on the chemical as a whole, in every instance, without flexibility ("**Whole Chemical Approach**"). This is a novel and non-scientific approach to risk assessment; it is not a regulatory approach designed to accurately address risks from the potential exposures associated with each specific condition of use, which is the Congressional intent of TSCA. Congress intended for EPA to have the flexibility to determine

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chloride, EPA evaluated 53 conditions of use within these categories, including: manufacturing (import); processing (repackaging, recycling, incorporation into a formula or mixture); industrial and commercial use as a laboratory chemical; plastic and rubber products manufacturing; and bonding agents for solvent welding. Methylene Chloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, 87 Fed. Reg. 67,901, 67,905-06 (Nov. 10, 2022).

which conditions of use should be evaluated based on potential for risk, and issue individual Risk Determinations for each use evaluated.

These new approaches necessitate industry to provide data to EPA – at exorbitant expense – to inform the agency about all uses prior to the Risk Evaluation, and to comment on expanded exposure assessments, even when those exposures are unlikely to occur or contribute significantly to overall risk or are related to a use that industry does not intend to pursue. By disregarding its duty to differentiate between the vastly distinct ways that chemicals are used, e.g. for use in a laboratory vs. in children's toys, EPA improperly tilts the scale toward finding unreasonable risk. This has already resulted in unreasonable Risk Determinations for every Risk Evaluation that EPA has conducted under the Whole Chemical Approach. It is difficult to imagine that EPA would find that *any* chemical does not pose unreasonable risk when evaluated as a whole substance, rather than by conditions of use.

Further, TSCA's directives for EPA to evaluate "all available information" related to "the likely duration, intensity, frequency and number of exposures under the condition of use of the chemical substance," surely includes well-established Occupational Safety and Health Administration ("**OSHA**") regulations requiring the use of personal protective equipment ("**PPE**") when considering chemical exposures to workers. But EPA's failure to account for compliance with existing regulatory

PPE requirements ("**No-PPE Assumption**") leads to faulty conclusions on chemical exposure and usurps other agencies' authorities. EPA must analyze the actual level of exposure to workers, which is not possible without evaluating how those exposures and any risks have already been mitigated by OSHA's relevant mandates for use of PPE and other worker protection measures.

Petitioners challenge the Rule as contrary to the plain language of TSCA and Congress's intent in adopting the 2016 Amendments to create a focused, systematic, and science-based Risk Evaluation Process, that allows EPA the flexibility to determine the conditions of use of a chemical that should be evaluated based on potential for risk. The Rule creates a wholly impracticable Risk Evaluation Process that wastes significant resources by requiring detailed review of every hypothetical circumstance in which a chemical has ever been or could be created, used or disposed of, resulting in the unreasonable, onerous, unnecessary and duplicative regulation of chemicals, without any flexibility. The Rule is arbitrary, capricious, not in accordance with law and should be set aside.

STATEMENT OF JURISDICTION

Respondents EPA and Administrator Michael S. Regan ("**Respondents**") issued the Rule pursuant to their authority under TSCA. 15 U.S.C. §§ 2605(b)(1)(A), (4)(B). The U.S. Courts of Appeals have jurisdiction to review final agency rules issued under TSCA. *Id*. § 2618(a)(1)(B). Venue is proper in this Court because

Petitioners ACC's, AFPM's, and API's principal places of business are in the District of Columbia.

The Rule was published on May 3, 2024, *see* 89 Fed. Reg. 37,028, and issued for purposes of judicial review on May 17, 2024. *See* 40 C.F.R. § 23.5(a); 15 U.S.C. § 2618(a)(2) (citing 28 U.S.C. § 2112). Petitioners ACC and TCC filed a timely petition for review in the Fifth Circuit Court of Appeals on May 24, 2024. Other Petitioners filed timely petitions for review challenging the Rule in the Fourth, Ninth, and D.C. Circuits. The Judicial Panel on Multidistrict Litigation selected this Court for the consolidation of all the petitions via Consolidation Order dated June 5, 2024. All petitions challenging the Rule were subsequently consolidated in this Court via orders dated June 7, 2024, June 17, 2024, and August 9, 2024.

STATUTES, RULES, AND REGULATIONS

The pertinent statutes and regulations are provided in the Addendum.

STATEMENT OF THE ISSUES

I. Whether the All Conditions of Use Approach is arbitrary, capricious, and not in accordance with law because it disregards the plain language and intent of TSCA, which requires the Administrator to determine which conditions of use raise the greatest potential for risk and should be evaluated.

II. Whether the Whole Chemical Approach is arbitrary, capricious, and not in accordance with law because it disregards TSCA's concept of "conditions of use"

which requires that EPA issue Risk Determinations for the specific uses of a chemical.

III. Whether EPA violated constitutional due process protections by failing to provide ascertainable certainty and clarity to the regulated community regarding the scope of future EPA chemical regulation as a result of the Whole Chemical Approach.

IV. Whether the No-PPE Assumption exceeds EPA's authority by disregarding the use of PPE by workers, even if required under worker protection laws, when evaluating chemical exposures.

STATEMENT OF THE CASE

In response to the growing use of industrial chemicals, Congress enacted TSCA in 1976. As Congress emphasized when it amended TSCA in 2016, the Act's purpose is to "fill a number of regulatory gaps" that existed in the regulation of chemicals that were widely sold, distributed, and utilized in manufacturing operations and industrial, commercial, and consumer products. *See* H.R. Rep. No. 144-76, at 28 (2015).

Section 6 of TSCA was amended to establish a review process for existing chemicals, which requires EPA to: (1) prioritize certain existing chemicals as "high

priority" or "low priority" ("**Prioritization**");[4] and (2) identify and assess hazards and exposures associated with certain uses of those designated high priority chemicals ("**Risk Evaluation**"), and issue a determination as to whether there is an unreasonable risk from any of the identified uses ("**Risk Determination**").

For chemicals designated as "high priority," EPA must conduct "risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation . . . under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). The "scope" of the Risk Evaluation must include "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider . . . ." *Id*. § 2605(b)(4)(D).

Each Risk Evaluation will include a tiered and targeted examination of potential hazards and exposures of a chemical under the "conditions of use" based on the best available science, while integrating hazard and exposure assessments, and considering uncertainty and variability, data quality, and environmental risks. *Id*. §§ (F)(i); 2625(h), (i). Then, based on the "best available science" and "weight

[4] Prioritization requires EPA to determine if an existing chemical substance is a high or low priority for risk evaluation. 15 U.S.C. § 2605(b)(1)(A). This requires "consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances . . . the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed." *Id.*

of the scientific evidence," EPA must issue a Risk Determination of whether the uses of the chemical identified by the Administrator pose unreasonable risk. *Id.* § 2605(b)(4)(A).

If, after the Risk Evaluation, EPA finds "no unreasonable risk" for each use reviewed, the Risk Evaluation Process ends. If, however, EPA finds "unreasonable risk" for one, some, or all of the uses reviewed, then EPA must move to Risk Management, which requires EPA to promulgate regulations within two years addressing the risks associated with *specific* uses of the chemical to the extent necessary so that the chemical no longer presents an unreasonable risk. *Id*. § (a) (emphasis added).

The 2016 Amendments required EPA to promulgate rules implementing the Risk Evaluation Process, which EPA did in 2017. *See* 82 Fed. Reg. 33,726. Under the 2017 Rule, EPA interpreted TSCA to require the agency to (1) select *which* chemicals to evaluate and under *what* conditions of use and (2) make final Risk Determinations on those conditions of use. Specifically, EPA concluded that it had "discretion to determine the conditions of use that [it] will address in its evaluation of the priority chemical, in order to ensure that the Agency's focus is on the conditions of use that raise the greatest potential for risk." *See* 82 Fed. Reg. 33,726 (*citing* 162 Cong Rec, S3519-S3520 (2016)). EPA further concluded that, identifying the "circumstances" that constitute a "condition of use" of each chemical

substance will "inevitably involve the exercise of some discretion . . . consistent with the objective of conducting a technically sound, manageable evaluation." *Id.* Finally, EPA vowed to "make individual risk determinations for all uses identified in the scope." *Id.*

In 2024, EPA abandoned this correct approach of concentrating on conditions of use with the greatest potential for exposure, as codified by Congress in TSCA. Under the Rule challenged here, EPA misinterprets the statutory requirements, now insisting that Congress commanded the agency to consider all conceivable scenarios, even those that are unlikely to occur or that present little potential for risk. 89 Fed. Reg. 37,035. There are no such provisions in the underlying statutory language. In fact, TSCA acknowledges the use of "sentinel exposures" (*i.e.*, focusing on conditions of use that contribute the greatest potential exposures) in 15 U.S.C. § 2605(b)(4)(F)(ii). EPA cites to several authorities in support of its changed interpretation, none of which bolster EPA's unauthorized, capacious expansion of the Risk Evaluation Process, including adopting the All Conditions of Use Approach, Whole Chemical Approach, and No-PPE Assumption. 89 Fed. Reg. 37,031, 37,035, 37,037.

SUMMARY OF THE ARGUMENT

Petitioners respectfully request that this Court grant the petitions for review and set aside the Rule for three principal reasons.

First, EPA's All Conditions of Use Approach is contrary to TSCA, which requires the Administrator to focus on those particular uses of a chemical that have the greatest potential for exposure in order to ensure a timely, thorough, and science-based review process. Additionally, the All Conditions of Use Approach impermissibly renders several provisions of TSCA inoperative and superfluous, including those related to scoping and federal preemption. Finally, the inherent structure of TSCA, including strict statutory deadlines, mandates that the Administrator prioritize uses for Risk Evaluation.

Second, EPA's Whole Chemical Approach for Risk Determinations is contrary to TSCA, which commands the agency to evaluate chemicals and issue Risk Determinations based on the "conditions of use" identified by the Administrator, and only regulate through Risk Management those uses of the chemical that are deemed to pose an unreasonable risk.

The Whole Chemical Approach will result in unreasonable Risk Determinations being driven by one singular use that poses an unreasonable risk, even if all other uses do not, as well as duplicative regulation of uses that are thoroughly regulated by existing federal frameworks. Finally, the Whole Chemical Approach violates due process protections because the regulated community will lack ascertainable certainty regarding which uses actually present an unreasonable risk.

Third, the Rule's No-PPE Assumption is contrary to TSCA's requirement that EPA "integrate and assess" all "available information on hazards and exposures" when conducting Risk Evaluations. Failing to account for the use of PPE also contravenes the statutory definition of "conditions of use" because speculative misuse/non-use of PPE and willful violations of other laws is not "intended, known, or reasonably foreseen" by EPA.

Further, automatically excluding the use of required PPE in an exposure assessment does not conform to the "best available science" provisions in 15 U.S.C. § 2625(h) because this assumption distorts the actual exposure potential. Risk Evaluations conducted with the No-PPE Assumption incorrectly and consistently assume a higher level of exposure than calculations considering existing OSHA PPE requirements, resulting in arbitrary Risk Determinations for every chemical for which EPA evaluates risks to workers.

STATEMENT OF STANDING

Petitioners have associational standing because: (1) their members have standing in their own right; (2) the interests they seek to protect are germane to their purpose; and (3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. *Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977).

Petitioners satisfy the first *Hunt* factor because their members are directly regulated by the challenged Rule. *See Twin Rivers Paper Co. LLC v. SEC*, 934 F.3d 607, 614 (D.C. Cir. 2019); 89 Fed. Reg. 37,028 (listing potentially affected entities who "are required to follow" the "process and requirements" in the Rule). In cases like this, when objects of governmental regulation "challeng[e] the legality of government action or inaction . . . , there is ordinarily little question that the action or inaction has caused [them] injury, and that a judgment preventing or requiring the action will redress it." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-62 (1992).

To be clear, there is a "substantial probability" that multiple members will suffer harm as a result of the Rule. *See Animal Legal Defense Fund, Inc. v. Vilsack,* 111 F.4th 1219, 1227 (D.C. Cir. 2024). Petitioners' members include chemical manufacturers, transporters, and distributors, and scientific organizations that are directly impacted by the regulatory regime under TSCA. *See* ACC Dec. at ¶¶4-5; TCC Dec. at ¶¶4-5; OxyChem Dec. at ¶¶4-6. The Rule governs the evaluation and regulation of chemical substances that are central to Petitioners' members' businesses and operations. Petitioners' members face imminent economic and operational harm in complying with the Rule. *See* ACC Dec. at ¶¶15-19; OxyChem Dec. at ¶¶8-10, 12 (describing impacts and compliance costs); *see also CropLife America v. EPA,* 329 F.3d 876, 883-84 (D.C. Cir. 2003).

Petitioners' member declarations demonstrate a "sufficient likelihood of economic injury to establish standing." *Clinton v. City of N.Y.*, 524 U.S. 417, 432-33 (1998). Additionally, they illustrate why Petitioners' members are injured by having to navigate the flawed and unlawful regulatory processes created by the Rule. *See* ACC Dec. at ¶¶15-19; OxyChem Dec. at ¶¶8-10, 12; *cf. NE Hub Partners v. CNG Transmission Corp.*, 239 F.3d 333, 342 (3d Cir. 2001); *Sayles Hydro Associates v. Maughan*, 985 F.2d 451, 454 (9th Cir. 1993) ("the hardship is the process itself").[5]

These injuries are fairly traceable to the Rule and are redressable by this Court. *See Lujan*, 504 U.S. at 560-61. Petitioners seek to enforce Congressional mandates regarding the scope of the Risk Evaluation Process. A favorable decision by this Court would remove a regulatory burden to the manufacture, development, sale and/or use of their products, which establishes redressability. *See Bennett v. Spear*, 520 U.S. 154, 169 (1997); *see also Energy Future Coal. v. EPA*, 793 F.3d 141, 144 (D.C. Cir. 2015).

Petitioners also satisfy the second and third *Hunt* factors for associational standing. Seeking the reasonable regulation of chemical substances is germane to

[5] Although these decisions analyzed hardship in the context of a ripeness analysis, the requirement to show hardship from delayed review under the ripeness doctrine "overlaps with the injury in fact facet of standing doctrine." *Navegar, Inc. v. United States*, 103 F.3d 994, 998 (D.C. Cir. 1997).

Petitioners' interests in advocating for and furthering the interests of the chemical industry. *See Am. Trucking Associations, Inc. v. Fed. Motor Carrier Safety Admin.*, 724 F.3d 243, 247 (D.C. Cir. 2013). Moreover, because Petitioners are not seeking monetary damages, but equitable relief (*i.e.*, vacatur of the Rule), participation of individual members is not required. *See Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 182 (D.C. Cir. 2017).

STANDARD OF REVIEW

The standard set forth in the Administrative Procedure Act ("**APA**") applies to the Court's review of this EPA procedural rule implementing TSCA. 15 U.S.C. § 2618(c)(1). Courts must set aside any agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Agency action is arbitrary and capricious if it:

> . . . has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

Further, the Court must "hold unlawful and set aside" an agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). In determining whether an agency has acted within the

statutory authority Congress granted to it, the Court must utilize "traditional tools of statutory interpretation" and apply the "best" reading of the statute without any deference to the agency's interpretation. *United States Sugar Corp. v. EPA*, 113 F.4th 984, 991-92 (D.C. Cir. 2024) (citing *Loper Bright v. Raimondo*, 144 S.Ct. 2244, 2266 (2024)).

ARGUMENT

I. EPA'S ALL CONDITIONS OF USE APPROACH VIOLATES TSCA AND IS ARBITRARY AND CAPRICIOUS.

In the Rule, EPA adopted a provision stating that it "*will not exclude conditions of use from the scope of the risk evaluation*, but a fit-for-purpose approach may result in varying types and levels of analysis and supporting information for certain conditions of use, consistent with paragraph (b) of this section." 40 C.F.R. § 702.37(a)(4) (emphasis added). This provision formalizes EPA's revised interpretation of TSCA: that Congress *mandated* that it review "all" conditions of use for a chemical substance during the risk evaluation process. However, nowhere in TSCA did Congress mandate this unwieldy review. Rather, TSCA makes clear that Congress intended EPA to review only those conditions of use that pose the greatest potential for risk and regulate only to the extent necessary.

A. The All Conditions of Use Approach is Contrary to the Plain Language of TSCA and Congressional Intent.

i. TSCA's Text Confirms that Congress Did Not Intend for the Agency to Review All Possible Conditions of Use.

EPA states that "the better reading" of TSCA's statutory text is that "EPA lacks authority to exclude conditions of use from the scope of the risk evaluation." 89 Fed. Reg. at 37,031 (further arguing that the agency lacks authority to select among those circumstances for inclusion or exclusion). Contrary to EPA's revisionist interpretation, the plain language of TSCA clearly demonstrates Congress's intent to allow the Administrator to determine which conditions of use pose the greatest potential for risk, and focus its Risk Evaluation Process primarily on those uses. *See U.S. v. Braxtonbrown-Smith*, 278 F.3d 1348, 1352 (D.C. Cir. 2002) (quoting *Estate of Cowart v. Nicklos Drilling Co*., 505 U.S. 469, 474 (1992) ("In construing a statute, the court begins with the plain language of the statute . . . . Where the language is clear, that is the end of judicial inquiry 'in all but the most extraordinary circumstances.'").

At the outset, a critical aspect of construing the plain language of a statute involves "giv[ing] effect, if possible, to every clause or word." *Lui v. SEC*, 591 U.S. 71, 89 (2020); *see also Ctr. for Biological Diversity v. U.S. Int'l Dev. Finance Corp.*, 77 F.4th 679, 688 (D.C. Cir. 2023). Here, giving effect to Congress's inclusion of the term "conditions of use" requires providing boundaries on the scope and extent

of the Risk Evaluations that the agency is required to conduct. *See* 15 U.S.C. § 2605(b)(4)(a). Omitting a term can be as telling of Congressional intent as interpreting the express statutory terms. Had Congress intended for EPA to review "all" conditions of use in every instance, it would have simply included the word "all" to modify "conditions of use" within the many requirements for Risk Evaluations in the statute.

Furthermore, this Court must presume that "Congress says what it means and means what it says." *Simmons v. Himmelreich*, 578 U.S. 621, 627 (2016); *Banks v. Booth*, 3 F.4th 445, 449 (D.C. Cir. 2021). Had Congress intended for EPA to review "all" conditions of use for every chemical substance, it would have said so. Congress could have chosen not to include the "conditions of use" concept altogether and instead instructed EPA to conduct Risk Evaluations for chemical substances, full stop. However, Congress did not do that; instead, it weaved the "conditions of use" concept throughout the relevant provisions with purpose and direction.

The statutory definition of "conditions of use" reinforces that Congress intended EPA to focus on only those uses of a chemical substance that pose the greatest risk. 15 U.S.C. § 2602(4). The term "conditions of use" is defined as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id*. § 2602(4) (emphasis added).

TSCA directs EPA to examine the hazards and exposures and determine the distinct circumstances under which the chemical can pose risks of injury to health and the environment as opposed to all uses. *See id*. § 2605(b)(2)(F)(i) (requiring that, when conducting risk evaluations, EPA must "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance"); *id*. § 2605(b)(2)(F)(iv) (requiring that EPA "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance"). *See also* Section II(A), infra, for a further discussion of EPA's evaluation of risks under individual conditions of use.

The ordinary meaning of the phrase "as determined" provides a clear and unambiguous directive, commanding EPA to determine the uses which should be prioritized and reviewed based on their different potential for exposure and contribution to risk. *See Southwest Airlines Co. v. Saxon*, 596 U.S. 450, 455 (2022) (statutory language must be read according to its "ordinary, contemporary, common meaning"); MERRIAM-WEBSTER DICTIONARY, "Determined" (defined as "to settle or decide by choice of alternatives or possibilities" or "to limit in extent or scope").

Other provisions of TSCA reinforce that Risk Evaluations must be conducted on a reasonable range of individual "conditions of use," rather than on every potential use of a chemical. *See Noble v. Nat'l Ass'n of Letter Carriers, AFL-CIO*, 103 F.4th 45, 50 (D.C. Cir. 2024) ("The [statutory] text must be read in the context

of the entire statute."). EPA's interpretation that it must take the All Conditions of Use Approach improperly renders numerous other provisions superfluous. *See C.F. Commc'n Corp. v. FCC,* 128 F.3d 735, 739 (D.C. Cir. 1997) (citing *Mail Order Ass'n of America v. USPS*, 986 F.2d 509, 515 (D.C. Cir. 1993)) (statutes must be construed "so that no provision is rendered inoperative or superfluous, void or insignificant").

For example, Section 6 of TSCA requires EPA to "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider. . . ." 15 U.S.C. § 2605(4)(D) (emphasis added). This scoping provision directing EPA to identify the specific "conditions of use" that it will assess during a Risk Evaluation is meaningless if EPA reviews all possible uses of the chemical substance.[6] Through the phrase "expects to consider," Congress clearly contemplated that EPA's discretion would determine which conditions of use are relevant and should be reviewed for a particular chemical substance, rather than suggesting EPA must evaluate all conditions of use. Therefore, EPA's interpretation

[6] Incredibly, in defending the "all uses" approach, EPA "acknowledge[es] that the Agency's expectations at the scoping phase may not always align perfectly with the conditions of use actually considered and assessed in draft and final risk evaluations." 89 Fed. Reg. 37,032.

mandating that "all" conditions of use be reviewed contradicts the plain language of this scoping provision.

The All Conditions of Use Approach is also contrary to the TSCA provision that requires that risk evaluations "describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration." *Id.* § 2605(b)(4)(F)(ii). This language highlights the necessity to focus risk evaluations on sentinel exposures or the uses that contribute the highest potential for exposure, resulting in harm to health or the environment. This demonstrates that Congress intended to allow the Administrator to scope the particular uses to be considered, and did not mandate review of all possible conditions of use.

Further, TSCA has a preemption provision that applies to "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope of the risk evaluation pursuant to section 6(b)(4)(D)." *Id.* § 2617(c) (emphasis added). Congress clearly intended that federal preemption would be applied to those specific conditions of use identified by EPA and included in the scope of a risk evaluation. Yet under the Rule, EPA cannot exclude any uses, and risk evaluations must include *all* conditions of use – meaning preemption would apply to all conditions of use *i.e.*, the entire chemical. If Congress intended to universally apply federal preemption to the whole chemical, it would have said so.

See Janko v. Gates, 741 F.3d 136, 140 (D.C. Cir. 2014) ("The preeminent canon of statutory interpretation requires us to presume that the legislature says in a statute what it means and means in a statute what it says there.") (internal citations and quotations omitted).

Finally, EPA's All Conditions of Use Approach is inconsistent with strict statutory timelines under which EPA must commence and complete its review of existing chemicals. *See* 15 U.S.C. § 2605(b)(4)(G) (requiring that risk evaluations be completed "no later than 3 years after the date on which the Administrator initiates the risk evaluation"). It would be infeasible for the agency to thoroughly and effectively review *every possible* scenario or condition of use of a chemical substance within a three-year time frame – indeed EPA previously suggested that it would not be able to meet its statutory deadlines if it evaluated all conditions of use,[7] and, in fact, it has missed many of its statutory deadlines under TSCA since implementing this approach.[8]

Congress included the "conditions of use" and scoping concepts in the statute to focus the extent and scope of the Risk Evaluation Process. EPA's interpretation

[7] *See* 82 Fed. Reg. at 33,728.
[8] *See* U.S. EPA, *Ongoing and Completed Chemical Risk Evaluations under TSCA,* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under (last updated Sept. 23, 2024).

that TSCA mandates a review of "all" conditions of use for every chemical substance cannot be squared with the statutory text.

ii. The Legislative History of TSCA Confirms that Congress Intended for EPA to Consider those "Conditions of Use" with the Greatest Potential to Pose Risk, Not All Conditions of Use.

The legislative history of TSCA reinforces what Congress made clear in the text: that EPA should focus on specific conditions of use, and not "all" conditions of use. *See Eagle Pharmaceuticals, Inc. v. Azar*, 952 F.3d 323, 338 (D.C. Cir. 2020) ("[E]xtrinsic materials, such as legislative history, have a role in statutory interpretation only to the extent they shed a reliable light on the enacting Legislature's understanding of otherwise ambiguous terms.") (internal quotations omitted). As explained below, EPA's approach improperly undermines the Congressional intent of TSCA. *See Braxtonbrown-Smith*, 278 F.3d at 1352 ("The court must avoid an interpretation that undermines congressional purpose considered as a whole when alternative interpretations consistent with the legislative purpose are available").

The history of the 2016 Amendments conveys Congress's intent to provide EPA with the discretion to limit the conditions of use to be evaluated. As stated by one of the bill's lead sponsors, Senator David Vitter (R. La.):

> The language of the compromise makes clear that EPA has to make a determination on all conditions of use considered in the scope but the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation of the priority chemical. This

> assures that the Agency's focus on priority chemicals is on conditions of use that raise the greatest potential for risk. This also assures that the Agency can effectively assess and control priority chemicals and meet the new law's strict deadlines. Without this discretion to focus chemical risk assessments on certain conditions of use, the Agency's job would be more difficult.

162 Cong. Rec. S3511, S3519 (2016) (emphasis added).

This excerpt leaves no doubt that the intent behind Congress's inclusion of the "conditions of use" concept was to allow for the Administrator to act on a chemical-by-chemical basis to select those conditions of use that may pose the greatest risk and to allow EPA to focus its efforts on evaluating the potential risks associated with those uses, while complying with statutory deadlines, and, if necessary, regulating those particular uses accordingly. Although Congress recognized that EPA would begin the review process by considering all uses identified in the scope, it simultaneously clarified that EPA would ultimately focus its Risk Evaluation on only those certain conditions of use that pose the greatest potential for risk.

B. EPA Did Not Adequately Justify Changing its Interpretation to Conclude That TSCA Requires Review of "All" Conditions of Use.

Independently, the Rule should be set aside because EPA did not adequately explain how it reached its conclusion and new interpretations. *See Dickson v. Sec'y of Defense*, 68 F.3d 1396, 1404 (D.C. Cir. 1995) ("The arbitrary and capricious standard of the APA 'mandat[es] that an agency take whatever steps it needs to

provide an explanation that will enable the court to evaluate the agency's rationale at the time of decision.'") (citation omitted); *see also Pub. Citizen v. Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993).

EPA's All Conditions of Use Approach totally departs from its prior interpretations in the 2017 Rule, without adequate justification. In the 2017 Rule, EPA adopted a definition of "conditions of use" identical to the statutory definition and discussed its interpretation of TSCA. *See* 40 C.F.R. § 702.33 (2017). EPA cited both the statute's text and the legislative history of the 2016 Amendments to conclude that it had "discretion to determine the conditions of use that [it] will address in its evaluation of the priority chemical, in order to ensure that the Agency's focus is on the conditions of use that raise the greatest potential for risk." *See* 82 Fed. Reg. 33,726 (citing 162 Cong. Rec. at S3519-20). EPA further explained that, identifying the "circumstances" that constitute a "condition of use" of each chemical substance will "inevitably involve the exercise of some discretion . . . consistent with the object of conducting a technically sound, manageable evaluation." *Id.*

EPA's Rule reversed its interpretation of the statute, but it failed to provide a reasoned explanation for its diametrically opposed position. *See Dickson*, 68 F.3d at 1404; *Pub. Citizen*, 988 F.2d at 197. EPA now interprets TSCA to mean that the agency lacks discretion to "exclude" or "select among" conditions of use, and may only use discretion when determining whether a "particular circumstance is

intended, known, or reasonably foreseen." 89 Fed. Reg. at 37,032. EPA lists several authorities as justification for the Rule, none of which mandate the All Conditions of Use approach.[9]

Accordingly, because EPA does not adequately justify the reasons for its changed interpretation of "conditions of use" and corresponding sections, the Rule is arbitrary and capricious and must be set aside. *See Dickson*, 68 F.3d at 1405 ("When an agency merely parrots the language of a statute without providing an account of how it reached its results, it has not adequately explained the basis for its decision.").

II. THE WHOLE CHEMICAL APPROACH VIOLATES TSCA AND THE FIFTH AMENDMENT'S DUE PROCESS CLAUSE.

The Rule requires that EPA make a "single" Risk Determination for the entire chemical, previously referred to as the "whole chemical approach." 89 Fed. Reg. at 37,035. Specifically, the Rule states:

> [a]s part of the risk evaluation, EPA will make a *single determination as to whether the chemical substance presents an unreasonable risk of injury to health or the environment*, without consideration of costs or other non-

[9] EPA cites to the following authorities as support for its changed interpretation in the Rule: (a) the statutory text and structure and Congressional intent; (b) the Ninth Circuit's 2019 decision in *Safer Chemicals, Healthy Families v. EPA*; (c) Executive Order 13990, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis; and (d) "[l]essons learned from the Agency's implementation of the risk evaluation program to date including feedback from the National Academies of Science Engineering and Medicine and scientific peer reviewers."

> risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use.

40 C.F.R. § 702.39(f)(1) (emphasis added).

The Whole Chemical Approach is contrary to TSCA because it disregards Congress's intent for EPA to review and evaluate chemicals based on how they are used. This approach also violates the due process protections of the regulated community by preventing regulated entities from understanding or having any notice regarding which uses of a chemical actually present an unreasonable risk and will be subject to regulation. Accordingly, the Rule should be set aside.

A. EPA's Whole Chemical Approach is Contrary to the Plain Language of TSCA.

The Whole Chemical Approach will result in EPA issuing one blanket Risk Determination per chemical. Thus, regardless of whether one, some, a substantial number, or all uses of that chemical pose an unreasonable risk, EPA would determine that the chemical as a whole presents an unreasonable risk. 89 Fed. Reg. 37,035 ("Where one or more conditions of use for the chemical present an unreasonable risk, the chemical substance itself necessarily presents an unreasonable risk."). This approach is contrary to TSCA's unambiguous command to determine whether a chemical substance presents unreasonable risk under its "conditions of use." 15 U.S.C. § 2605(b)(4)(A). Nowhere in TSCA's text did Congress mandate review of

the chemical as a whole. In fact, the statute does not even use phrases like "whole chemical," "single risk determination" or "chemical itself."

To interpret a statute, the Court first must look to the plain language of the statute. *See Braxtonbrown-Smith*, 278 F.3d at 1352 (quoting *Estate of Cowart*, 505 U.S. at 474 ("Where the [plain] language [of a statute] is clear, that is the end of judicial inquiry 'in all but the most extraordinary circumstances."). Here, the plain language of TSCA makes clear that Risk Determinations are to be made based on the conditions of use (*i.e.* how a chemical is manufactured, processed, distributed in commerce, used, or disposed of) as decided upon by the Administrator, and not based on the chemical as a whole in every instance without flexibility. Accordingly, for the reasons described below, the Court's inquiry begins and ends with the unambiguous language of TSCA.

TSCA requires EPA to make a Risk Determination of unreasonable risk or no unreasonable risk following completion of the Risk Evaluation. 15 U.S.C. § 2605(b)(4)(A). The statute requires the Administrator to "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use." *Id.* (emphasis added). TSCA does not instruct EPA to evaluate the total risks of a chemical, but each risk, based upon the individual ways the chemical is used.

When read together with other provisions of TSCA emphasizing "conditions of use," namely the scoping and federal preemption provisions, *see infra* Part I.A, it is clear that Congress did not intend to allow EPA to ignore the distinction among such uses by making the risk determination at the whole chemical level. *See e.g., Eagle Pharmaceuticals*, 952 F.3d at 332 (statute must be interpreted "as a symmetrical and coherent regulatory scheme, and fit, if possible, all parts into a harmonious whole.") (internal citations omitted). Rather, Congress intended that Risk Evaluations, and their resulting Risk Determinations, be tied to those specific, individual uses of a chemical substance that were determined relevant by the Administrator.

By including the concept of "conditions of use" within TSCA and the statutory provision on Risk Determinations, Congress clearly intended to tie Risk Determinations to the circumstances under which a chemical is likely to be processed or used. The Whole Chemical Approach, however, completely reads out the concept of "conditions of use" from 15 U.S.C. § 2605(b)(4)(A). EPA disregards potential exposures to the substance under specific conditions of use, and therefore EPA cannot differentiate between the uses of the chemical that present the risk, and those that do not. Said another way, a Whole Chemical Approach Risk Evaluation implies a focus on the risk characterization of the substance, and removes evaluation of the potential exposures to the substance (and therefore risks from the substance)

under actual use cases. Such a statutory reading contradicts basic principles of statutory construction and cannot be upheld. *See Natural Resources Defense Council, Inc. v. EPA,* 822 F.2d 104, 113 (D.C. Cir. 1987) ("To read out a statutory provision of a clause setting forth a specific condition or trigger to the provision's applicability is. . . , an entirely unacceptable method of construing statutes").

Similarly, Congress required that, when conducting risk evaluations, EPA must "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance," 15 U.S.C. § 2605(b)(2)(F)(i), and that it "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance." *Id.* § 2605(b)(2)(F)(iv). Had Congress instead intended for EPA to determine risk for the chemical as a whole, it would not have included the phrase "the conditions of use of" in either of these provisions.

Finally, the Whole Chemical Approach is contrary to the federal preemption provision of TSCA related to the regulation of chemicals for which EPA makes an "unreasonable" Risk Determination. *See* 15 U.S.C. § 2617(c)(3). Specifically, federal preemption applies to "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to section 2605(a)." *Id.* (emphasis added). Section 2605(a) in turn requires the Administrator to issue Risk Management rules to regulate chemicals for

which an unreasonable Risk Determination is issued. *Id*. § 2605(a). Read together, federal preemption applies to those particular conditions of uses that are identified in the scope of the Risk Evaluation, not to the whole chemical, *see id*. § 2617(c)(2), because EPA is required to issue Risk Determinations for particular uses, not the whole chemical, and a finding of no unreasonable risk from a condition of use is considered a final agency action.

For these reasons, the Whole Chemical Approach is an unreasonable interpretation of TSCA, and the only harmonious reading requires individual Risk Determinations based on the distinct conditions of use identified in the scope. Nowhere in the statute did Congress intend, direct, or require EPA to make a singular Risk Determination for each existing chemical being evaluated. If this is the process Congress had intended, it would not have included scoping and preemption provisions focusing on the conditions of use.

B. TSCA's Purpose and Legislative History Reinforce What the Text Makes Plain.

The legislative history of TSCA, as originally enacted, and the 2016 Amendments further demonstrate that Congress intended for use-by-use Risk Determinations and not the Whole Chemical Approach. *See Nat'l Treasury Emps. Union v. Fed. Lab. Rels. Auth.*, 691 F.2d 553, 559 (D.C. Cir. 1982) ("In construing ambiguous terms of legislation, the intent of Congress is paramount, and this intent may be appropriately ascertained from relevant legislative history.").

TSCA was not intended to regulate chemical substances for uses that are already regulated under other statutes. *See* 122 Cong. Rec. S16802 (1976); *id*. at S16806 (statement of Sen. Tunney) ("The proposal . . . was viewed largely as an environmental bill designed to plug gaps that existed in the environmental control framework."). EPA's Whole Chemical Approach is directly contrary to this statutory purpose because it reads out sections of TSCA that were intended to focus the scope of EPA's review of existing chemicals.

When Congress enacted TSCA, the drafters recognized that existing federal laws governed certain aspects of chemical regulation, including "air and water laws" and laws governing the "workplace" and "consumer products" but that there were "no existing statutes which authorize the direct control of industrial chemicals themselves for their health or environmental effect . . ." H.R. Rep. No. 114-176, at 166 (2015). The intent of the statute and the policy goals behind it remained "intact" through the 2016 amendments. S. Rep. No. 114-67, at 7 (2015). Specifically, House Report 114-176 states:

> H.R. 2576 reinforces TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals. The Joint Explanatory Statement of the Committee of Conference for the legislation, which is now Title I of TSCA, clearly states that ''[t]he conferees have drawn from both the Senate bill and the House amendment to assure that overlapping or duplicative regulation is avoided.''

Under the flawed Whole Chemical Approach, EPA could regulate any use of the chemical, even if that imposes duplicative regulation of specific uses of the chemical that are regulated under existing federal environmental frameworks, contrary to Congressional intent, and over-regulate uses that pose no unreasonable risk because they are already controlled to an acceptable risk level under other statutes.

For example, even if EPA determines that processing of a certain chemical used in a closed system is already comprehensively regulated under the OSH Act, it could still decide to regulate that use as part of the Whole Chemical Approach (e.g. the use of perchloroethylene as a catalyst regenerator in petroleum refining processes). Conversely, under the best reading of the statute, where Risk Determinations are based on individual conditions of use, EPA would be permitted to make Risk Determinations of unreasonable risk for specific conditions of use of the chemical, and refer any conditions of use that are better or already regulated under existing requirements to the respective agencies/offices with such jurisdiction.

Moreover, under the Whole Chemical Approach, EPA could decide to regulate particular uses of a chemical that do not present an unreasonable risk (simply based on the type of use, not based on other regulations), as a way of addressing the risk of the "whole chemical," even if the basis for the Risk

Determination is an unreasonable risk posed by just one, separate use. Such an illogical possibility was not contemplated in the adoption of TSCA.

C. The Whole Chemical Approach Violates Due Process Protections of the Regulated Community.

EPA's Whole Chemical Approach deprives stakeholders and the regulated community of meaningful notice about what uses will ultimately be subject to regulation through Risk Management. *See Satellite Broad Co. v. FCC*, 824 F.2d 1, 3 (D.C. Cir. 1987). EPA is failing to make it sufficiently clear, with "ascertainable certainty" its expectations of the regulated community as a result of the Whole Chemical Approach, which violates due process. *Trinity Broad. of Fla., Inc. v. FCC*, 211 F.3d 618, 628 (D.C. Cir. 2000) (citing *General Elec. Co. v. EPA*, 53 F.3d 1324, 1328-29 (D.C. Cir. 1995)) (explaining an agency provides proper notice if, "by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with ascertainable certainty, the standards with which the agency expects parties to conform").

The Whole Chemical Argument violates due process protections of the regulated community because it is unclear which conditions of use will ultimately be regulated following a singular Risk Determination. In fact, under this Approach, EPA could decide to regulate conditions of use that would be deemed to pose no unreasonable risk under a Use-by-Use Approach and for which no exposure data or information has been provided to the agency to conclude that the use poses a risk.

As a result, the regulated community is left with more questions than answers and ultimately must "wait and see" how EPA chooses to apply the Whole Chemical Approach in addressing and managing the risks identified in a singular Risk Determination. For example, under the Whole Chemical Approach, a regulated entity that utilizes or sells a certain chemical substance under a condition of use that does not actually pose an unreasonable risk would be left to wonder how strictly it could be regulated and face losses due to market deselection until EPA makes a final regulatory Risk Management decision.

Accordingly, because the regulated community is not left with "ascertainable certainty" as to how its activities may be regulated and the standards with which it may be expected to confirm, the Whole Chemical Approach violates due process protections. *See Trinity Broad. of Fla., Inc.*, 211 F.3d at 628.

III. EPA IGNORED DIRECTIVES UNDER TSCA BY DISREGARDING REQUIRED USE OF PERSONAL PROTECTIVE EQUIPMENT IN CONDUCTING RISK EVALUATIONS.

The Rule added the following new subsection regarding required components of Risk Evaluations:

> In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information, including known and reasonably foreseen circumstances where subpopulations of workers are exposed due to the absence or ineffective use of personal protective equipment. *EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination*.

40 C.F.R. § 702.39(f)(2) (emphasis added).

Stated differently, EPA will assume noncompliance with existing OSHA PPE requirements when evaluating worker exposures for manufacturing and industrial uses of chemicals. EPA's No-PPE Assumption ignores TSCA's mandate to consider all "available information on hazards and exposures" and improperly displaces OSHA's authority to regulate workplace conditions.

A. Failure to Consider Existing PPE Requirements for Workers Is Contrary to TSCA.

i. EPA Must Consider All "Available Information" Regarding Exposures, Including Existing Regulatory Requirements.

EPA "shall" assess all "available information on hazards and exposures" as well as "the likely duration [and] intensity . . . of exposures under the conditions of use of the chemical substance." 15 U.S.C. § 2605(b)(4)(F)(i), (iv). Risk evaluations must also "describe the weight of the scientific evidence for the identified hazard and exposure." *Id*. § (v). EPA "shall take into consideration . . . hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(h). "Conditions of use" means "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id*. § 2602(4). While TSCA does not define "reasonably available information," EPA promulgated its own definition, which

includes "information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations." 40 C.F.R. § 702.33.

Use of PPE by workers to reduce chemical exposure is clearly relevant to the analysis of exposure and its contribution to workplace risk. PPE is often required by OSHA regulations, *see, e.g.*, 29 C.F.R. § 1910.1052 (requiring use of work practice controls, such as PPE, in workplaces with exposures to methylene chloride), and Congress requires every employer to "comply with occupational safety and health standards promulgated under" the Occupational Safety and Health Act ("**OSH Act**"). 29 U.S.C. § 654(a)(2). By turning a blind eye to these existing OSHA regulatory requirements, the Rule will result in Risk Evaluations that fail to comply with TSCA's mandate that EPA "assess available information" because the Rule fails to consider "available information on hazards and exposures," such as existing requirements mandating the use of PPE for certain uses. 15 U.S.C. § 2605(b)(4)(F)(i); *see also Smith v. Spizzirri*, 601 U.S. 472, 472 (2024) (quoting *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998)) ("The statute's use of the word 'shall' 'creates an obligation impervious to. . . discretion.'"). The Rule's requirement to ignore the use of required PPE also conflicts with Congress's directive to use available information. *See* S. Rep. No. 114-67, at 9 (stating that Congress intended "that EPA systematically search for and identify relevant information that is available").

The Rule's failure to consider the use of PPE, which reduces exposure, conflicts with EPA's duty to evaluate the duration and intensity of exposures. 15 U.S.C. § 2605(b)(4)(F)(iv). The Rule also ignores the statutory definition of "conditions of use," because speculative misuse or non-use of PPE in every case is not "intended, known, or reasonably foreseen" by EPA—indeed, it is *illogical*. *Id*. § 2602(4). Further, the Rule does not comply with EPA's own regulatory definition of "reasonably available information," because the agency clearly can "reasonably generate, obtain, and synthesize" existing regulatory regimes that require the use of PPE in workplaces with chemical exposures. *See* 40 C.F.R. § 702.33.

Ignoring the use of PPE will cause cascading noncompliance with TSCA. Without considering the widespread use of PPE under existing regulatory requirements, Risk Evaluations conducted under the Rule will not comport with the "weight of the scientific evidence" or "best available science" standards because they will overestimate risks by overestimating exposure, leading to inaccurate Risk Management of chemicals not based in science. *See* 15 U.S.C. §§ 2605(b)(4)(F)(v); 2625(h); *see also* ACC, Comment Letter at 7.

EPA also disobeys TSCA's requirement to consult and coordinate with other federal agencies to impose the fewest "burdens of duplicative requirements on those subject" to TSCA. *Id*. § 2608(d). EPA has long described the OSH Act as the "primary statute for protecting the health and safety of workers" that provides "broad

authority" to regulate chemical risks in the workplace. *See* 1,3-Butadiene; Decision To Report to the Occupational Safety and Health Administration, 50 Fed. Reg. 41,393, 41,398 (Oct. 10, 1985). Rather than defer to OSHA's primary authority, the Rule instead uses the overlap between chemical regulation under TSCA and OSHA's authority to regulate workplace safety to overreach into an area that Congress delegated to OSHA for regulation. *See Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 650 (1990) (quoting *Fed. Mar. Comm'n. v. Seatrain Lines, Inc.*, 411 U.S. 726, 745 (1973)) ("[I]t is fundamental 'that an agency may not bootstrap itself into an area in which it has no jurisdiction.'"). .

ii. Unreasonable Risk Determinations for Every Chemical Are Contrary to TSCA and Congress's Intent.

The consequence of ignoring widespread use of PPE to comply with workplace regulations is that EPA will find an unreasonable risk to workers for nearly every chemical substance EPA evaluates. *See* ACC, Comment Letter at 7. This result is inconsistent with both the plain language of TSCA and Congress's intent, because Risk Evaluations conducted without consideration of the use of PPE will assume a much higher level of exposure to workers than the level that actually exists. *See, e.g.*, Final Revised Unreasonable Risk Determination for 1-Bromopropane at 3 ("EPA has determined that the risk determination [must] not rely on assumptions regarding the use of personal protective equipment (PPE).").

However, TSCA requires EPA to "conduct risk evaluations . . . to determine *whether* a chemical substance presents an unreasonable risk of injury to health or the environment. . . under the conditions of use." 15 U.S.C. § 2605(b)(4)(A) (emphasis added). The statute also states that "a determination by the Administrator . . . that a chemical substance does not present an unreasonable risk of injury to health or the environment" is considered a "final agency action." *Id*. § 2605(i).

The Rule would impermissibly read these provisions out of the statute, because the No-PPE Assumption assumes much higher exposure levels, resulting in arbitrary determinations of unreasonable risk for nearly every chemical for which EPA evaluates risk to workers. *See Duncan v. Walker*, 533 U.S. 167, 174 (2001) (quoting *United States v. Menasche*, 348 U.S. 528, 538–39 (1955)) (finding that courts should "give effect. . . to every clause and word of a statute"); *see also Young v. UPS, Inc.*, 575 U.S. 206, 226 (2015) (quoting *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001)) (noting that "a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause is rendered superfluous, void, or insignificant"). This misinterpretation will inevitably lead to arbitrary regulations of workplace exposure to TSCA-regulated chemicals, an absurd result contrary to Congressional intent that fails to give the regulated community certainty regarding which regulations apply between those issued by EPA and OSHA.

Further, Risk Evaluations conducted without consideration of PPE exposure reduction are inconsistent with EPA's own prior policy towards conditions of use. *See* 89 Fed. Reg. at 37,033 (noting that EPA will not review "intentional misuse of a chemical as a condition of use" because intentional misuse scenarios are "unsubstantiated, speculative or otherwise not likely to occur"). Speculative misuse of chemical substances goes beyond the scope of TSCA and is inconsistent with TSCA's legislative history. *See* S. Rep. No. 114-67, at 7 (stating that the term "conditions of use . . . is not intended to include intentional misuse of chemicals"). So too are speculative failures to follow workplace safety requirements.

B. EPA's Authority Under TSCA Does Not Displace OSHA's Authority to Regulate Workplace Exposures.

i. EPA Must Account for OSHA's Existing Regulatory Requirements for Workers.

Unlike EPA, OSHA is the federal agency tasked with regulating the workplace. 29 U.S.C. § 651(b)(3). By statute, OSHA must "by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard." *Id*. § 655(a). Congress required every employer to comply with those standards. *See id.* § 654(a)(2).

OSHA has repeatedly exercised this authority by issuing regulations to protect workers from chemical hazards in the workplace, including by the creation of standards that contain Permissible Exposure Limits ("**PELs**") for certain

chemicals.[10] *See, e.g.*, 29 C.F.R. § 1990.142(a)(2)(i). OSHA requires that employers achieve PELs "primarily through engineering and work practice controls" including "respiratory protection, protective clothing and equipment." *Id*. OSHA has set PELs for approximately 500 chemicals, many of which overlap with chemicals for which EPA has conducted or is conducting Risk Evaluations under TSCA. *See* 29 C.F.R. § 1910.1000; OSHA, *Chemical Hazards and Toxic Substances*, https://www.osha.gov/chemical-hazards (last visited Oct. 10, 2024).

Despite lacking OSHA's expertise in occupational safety, health, and industrial hygiene practices, the Rule disregards existing OSHA regulations that require the use of PPE. *See* 40 C.F.R. § 702.39(f)(2). This is already happening.[11] For example, EPA recently finalized a rule that requires employers to limit inhalation exposures to methylene chloride to 2 ppm[12] based on the No-PPE Assumption[13] and to comply with certain PPE requirements. 40 C.F.R. § 751.109.

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[10] OSHA has acknowledged that many PELs are outdated; however, the proper path forward is for EPA to refer risks that could be mitigated through work practice standards to OSHA, and for OSHA to update PELs accordingly. *See* Permissible Exposure Limits – Annotated Tables, https://www.osha.gov/annotated-pels (last visited 10/10/24); 15 U.S.C. § 2608(a).

[11] *See, e.g.*, EPA, *EPA Announces Path Forward for TSCA Chemical Risk Evaluations* (June 30, 2021), https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.

[12] Expressed as an eight-hour time-weighted average.

[13] *See* Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 39,254, 39,292 (May 8, 2024) ("[C]ompliance with regulatory controls on workplace exposures to methylene chloride. . . cannot be assumed.").

EPA did so despite an overlapping OSHA regulation that requires employers to limit inhalation exposures to methylene chloride to 25 ppm[14] and take steps to limit exposure risks, including via PPE. 29 C.F.R. § 1910.1052.

The No-PPE Assumption is also currently a critical factor causing EPA to arbitrarily overestimate risks exposure, and therefore risk, at the Risk Evaluation and Risk Determination stages. For instance, the draft Risk Evaluation for formaldehyde includes an "occupational exposure value" of 0.011 ppm[15] (even though naturally occurring indoor air concentrations are much higher, ranging from 0.02 to 4 ppm), when OSHA's preexisting PEL for the same chemical is significantly higher at 0.75 ppm. 29 C.F.R. § 1910.1048. Similarly, the draft Risk Determination for 1,4 dioxane includes an Existing Chemical Exposure Limit of 0.055 ppm,[16] when OSHA's PEL for the same chemical is 100 ppm. 29 C.F.R. § 1910.1000 at Table Z-1. EPA's promulgation of these conservatively low exposure limits without considering OSHA's pre-existing PEL and PPE risk mitigation measures fails to comply with TSCA's mandate to evaluate all "available information on hazards and exposures." 15 U.S.C. § 2605(b)(4)(F)(i). This practice results in EPA arbitrarily overestimating

[14] Expressed as an eight hour time-weighted average.
[15] EPA, *Draft Human Health Risk Assessment for Formaldehyde* (March 2024) https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-human-health-risk-assessment-public-release-hero-march-2024.pdf.
[16] EPA, *Existing Chemical Exposure Limit (ECEL) for Occupational Use of 1,4-Dioxane* (Aug. 8, 2023), https://downloads.regulations.gov/EPA-HQ-OPPT-2022-0905-0039/content.pdf.

exposures and risks that have already been addressed by the agency tasked with worker protection. *Id*.

ii. TSCA Is Not, and Was Not Intended to Be, a Worker Protection Law.

TSCA mandates that EPA *must* evaluate the risks to "potentially exposed or susceptible subpopulations," which *may* include workers where they are "identified as relevant to the risk evaluation by the Administrator, under the conditions of use." 15 U.S.C. §§ 2605(b)(4)(A), 2602(12). In other words, if EPA determines that workers are not relevant to the Risk Evaluation under the identified conditions of use, EPA is not required to assess risks to workers. Accounting for the use of PPE and the regulation of workplace exposure by OSHA are obvious reasons that potential workplace exposure does not require EPA to assess risks to workers in every instance. But as a result of the Rule, EPA has focused on workers in all eleven Risk Evaluations it has finalized to date.[17]

Further, TSCA recognizes that regulation by EPA as a result of a faulty Risk Evaluation is not the best approach if regulation by another agency, such as OSHA, is more appropriate. The Rule ignores this option by assuming workers are not following OSHA regulations. Specifically, TSCA contains a mechanism for EPA to refer risks to other agencies where EPA determines that the risk "*may* be prevented

[17] *See Ongoing and Completed Chemical Risk Evaluations Under TSCA, supra.*

or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator." 15 U.S.C. § 2608(a)(1) (emphasis added). Notably, this is a very low bar, as Congress could have required referral when EPA finds that risk "would" or "may likely" be prevented or reduced by another agency, but it did not. Regardless, if the other agency acts upon EPA's referral, TSCA prohibits EPA from further consideration of those risks. *Id*. § 2608(a)(2). If the other agency already regulates the condition of use, or appropriate portion thereof, EPA should consider those regulations in its Risk Evaluation.

Applying this in context, TSCA requires EPA to refer regulation of TSCA chemicals that pose unreasonable risks to workers to OSHA if regulation under the OSH Act *may* prevent or reduce risks of chemical exposure in the workplace. And only if the referral agency fails to act may EPA proceed to regulate those risks to workers. Yet, EPA impermissibly reads this process out of the statute by forbidding consideration of preexisting OSHA regulations, including PELs and work practice controls such as PPE. *See Duncan*, 533 U.S. at 174.

In addition to the express language of TSCA, Congress explicitly stated in a report accompanying the original draft legislation that it did not intend for EPA to evaluate risks to workers in every instance or turn TSCA into a full worker protection law. Specifically, it stated:

> The requirements prescribed by the Administrator under [TSCA] may provide protection for employees in the workplace…[; however,] none

> of the authorities [under TSCA] should be construed as authorizing the Administrator to issue workplace standards directly regulating such matters….Such direct regulation of the workplace falls under the jurisdiction of the Occupational Safety and Health Act of 1970 not under this bill.

H. Rep. NO. 94-1341, at 34 (1976). Congress intended "that any requirement prescribed under [TSCA] be the least burdensome possible for those subject to the requirement and for society while providing an adequate margin of protection against the unreasonable risk." *Id*.

The intent to avoid overburdensome, duplicative regulation continued during the drafting of the 2016 Amendments. There, Congress noted that its goal was to "encourage decisions that avoid confusion, complication, and duplication." H. Rep. No. 114-176, at 28. The Committee on Energy and Commerce instructed EPA to "respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety. Specifically, the Committee does not intend for the implementation of TSCA to conflict with or disregard Occupational Safety and Health Administration's hierarchy of controls." *Id*. at 28–29. The Rule directly contradicts this intent by disregarding OSHA's existing requirements regarding use of PPE in workplaces with certain chemical exposures.

CONCLUSION

For the foregoing reasons, Petitioners respectfully request this Court grant the petitions for review and vacate the Rule as arbitrary, capricious, not in accordance with law, and in excess of EPA's statutory authority.

Respectfully submitted,

/s/ Rafe Petersen
Rafe Petersen
Meaghan Colligan
HOLLAND & KNIGHT LLP
800 17th Street N.W.
Suite 1100
Washington, D.C. 20006
Rafe.Petersen@hklaw.com
Meaghan.Colligan@hklaw.com
Tel.: (202) 419-2481

Attorneys for Petitioners Texas Chemistry Council and American Chemistry Council

/s/ David Y. Chung
David Y. Chung
CROWELL & MORING LLP
1001 Pennsylvania Avenue N.W.
Washington, D.C. 20004
DChung@crowell.com
Tel.: (202) 624-2567

Attorney for Petitioners American Fuel & Petrochemical Manufacturers and American Petroleum Institute

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), I hereby that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and the Court's order dated September 9, 2024 because it contains 10,717 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), according to the count of Microsoft Word.

I further certify that this brief complies with the typeface and type-style requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Times New Roman font.

/s/ Rafe Petersen
Rafe Petersen

/s/ David Y. Chung
David Y. Chung

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of October, 2024, the foregoing Opening Brief of Petitioners has been served on all registered counsel through the Court's electronic filing system.

/s/ Rafe Petersen
Rafe Petersen

/s/ David Y. Chung
David Y. Chung